

Appl. No. 10/013,980
Amdt.AF. dated January 14, 2005
Reply to Office Action of November 16, 2004

REMARKS

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed November 16, 2004. Claims 1 and 59-86 are pending. Claim 67 has been amended. Support for the amendment to the claim can be found in the specification and drawings as originally filed. No new matter has been added. Reconsideration and reexamination are respectfully requested.

Allowable Subject Matter

Applicants thank the Examiner for indicating that claims 73, 74, 78, 82, 83, and 85 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Objection to the Specification

The specification is objected to because the reference to an earlier application has not been updated. The above amendment to the specification overcomes this objection.

Objections to the Claims

Claim 67 is objected to for lacking antecedent basis. The claim has been amended to depend from claim 66 as suggested by the Examiner.

Rejections under 35 U.S.C. § 102

Claims 1, 59, 61, 64, 66-69, 71, 75-77, 79-81 and 84 are rejected as being anticipated by Healy (US 4,757,817). The Examiner asserts that Healy discloses a lead electrode assembly including electrode 13, backing layer 14 and fin 10b projecting from the backing layer. Applicants respectfully traverse the rejection.

The device of Healy is an adhesive electrode pad for attaching an electrode to a patient's skin. Healy teaches the "electrode pad is readily manually accessible and can be successively peeled off from the plastic carrier sheet 10 when it is to be used." See column 3, lines 15-18. Healy also teaches "tab section 10b releasably covering the bottom adhesive surface of the tab 15. The two sheet sections 10a, 10b can be removed from the pad independently of one another." See column 4, lines 26-29.

Independent claim 1 recites "the backing layer forms the fin and the fin projects from the backing layer." By the Examiner's explanation, the main body portion 14 must be the "backing layer". Claim 1 also recites that the backing layer is placed over the top of the electrode.

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However, as shown in the cross section of Figure 6 by Healy, the electrode, which is element 13, is disposed over top of the main body portion 14. Healy explains:

The present pad 11 generally comprises a pad of pliable material including a main body portion 14 and a tab 15. An electrode 13 including an electrical fitting 16 is carried on the substantially flat top surface of the main portion 14 while a conductive jelly 17 is carried on the bottom surface of the main portion. The conductive jelly is in electrically conductive relationship through the main portion 14 of the pad with the electrode 13.

(Healy at column 3, lines 20-27.) It can be seen that the conductive jelly is on the bottom of the backing layer, with the electrode placed over the top thereof such that the jelly provides electrical conduction through the backing layer. This is a distinct structure from that recited. As such, the structure recited in claim 1 is not disclosed by Healy.

With respect to claim 75, the claims recites that the electrode has a discharge face and an opposing face, with the backing layer attached to the opposing face of the electrode. As highlighted above, the electrode is secured on its discharging side to the back or top of the backing layer. Again, the structure disclosed by Healy is distinct from that of the claim.

With respect to claim 81, the backing layer is disposed over the first face of the electrode. To achieve a correspondence with that disclosed by Healy, this recited passage would have to be understood to call for the bottom of the electrode to be the first face. Then, claim 81 also recites that a flexible fin is disposed on the backing layer, the fin extending away from the first face of the electrode. As just noted, however, the first face of the electrode would be the bottom or discharge face of the electrode. Thus, by the Examiner's reading, a fin would have to extend away from the discharge face of the electrode for Healy's external electrode, which would render the device unusable, as the fin would interfere with the required attachment of the Healy external electrode to a patient's skin. Applicants believe that this interpretation of the reference is untenable.

Independent claims 1, 75, and 81 recite in the preamble that the lead electrode assembly is implantable. The Examiner asserts that the preamble in the instant claims is merely an intended use. It appears to Applicants that this statement is a reference to the positioning of the defibrillator as subcutaneous. However, whether subcutaneously placed or not, an implantable electrode is certainly understood by one of skill in the art as having different requirements (i.e.

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size, scalability, durability, biocompatibility) than a non-implantable electrode. This distinction is made quite clear in the present instance since, as noted, a jelly is required for conduction. This jelly would, in the body, likely be dissolved away from the electrode. Further, a small aperture through the backing layer is used by Healy, which would intensely focus applied energy if used within the body, likely damaging tissue during use.

MPEP § 2111.02, under the heading PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE, quotes *In re Schreiber* 44 USPQ2d 1429 in stating that if "a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." Applicants submit that the structure disclosed by Healy is unsuitable for, and therefore (particularly in the medical device field) incapable of performing the intended use of being implanted and used for electrical stimulation. Healy specifically teaches his adhesive pad for external use on a patient's skin.

With respect to the instant claims, Applicants submit that "the claim preamble is 'necessary to give life, meaning, and vitality' to the claim" and thus "the claim preamble should be construed as if in the balance of the claim." See MPEP § 2111.02, quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.* 51 USPQ2d 1161. Applicants submit that the recitation in the instant claims of the electrode assembly being implantable distinguishes the claimed device from the external electrode of Healy.

In light of the above remarks, it is believed that each of independent claims 1, 75, and 81, along with dependent claims 59, 61, 64, 66-69, 71, 76-77, and 79-80 are patentable over the cited reference.

Applicants address independent claim 84 separately, as it does not specifically recite an implanted electrode. Claim 84 recites a backing layer disposed over the first face of the electrode. As noted above, to achieve correspondence with the disclosure of Healy, this recited element calls for the bottom or discharge face of the electrode in Healy to be the recited "first face". The claim also recites "an appendage disposed on the first face of the electrode and extending through the backing layer." Applicants see no such appendage in the disclosure of Healy. Instead, the Examiner points to an element on the opposite side of the electrode (fitting post 16). Healy thus does not teach or suggest an appendage disposed on the first face of the electrode and extending through the backing layer, as is recited in claim 84. Applicants submit

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that Healy fails to teach or suggest the recited structure of claim 84, and withdrawal of the rejection is respectfully requested.

Claims 1, 59-62, 64, 68, 69, 71, 72, 75-77 and 79-81 are rejected as being anticipated by Bishay et al. (US 6,272,385). The Examiner asserts that Bishay et al. disclose a lead electrode assembly including an electrode 24, a backing layer 22 or 42, and a fin 32 or 48, and thus anticipates the claimed invention. Applicants respectfully traverse the rejection.

As stated above with respect to the Healy reference, independent claims 1, 75, and 81 recite in the preamble that the lead electrode assembly is implantable. The Examiner asserts that the preamble in the instant claims is merely an intended use. Again, Applicants refer to the plethora of differences noted above including size, durability, biocompatibility, and the like that distinguish implantable electrodes from non-implantable electrodes. With specific reference to Bishay et al., Applicants note the size of the electrode as suggested in Figures 4A and 4B, which covers a large portion of the patient's pectoral region. Such a large electrode would not be considered "implantable". Furthermore, Bishay et al., like Healy, rely on a conductive gel to provide an interface between the electrode and the patient. Applicants submit that the structure of Bishay et al.'s electrode is not capable of performing the intended use of being implanted outside a patient's ribcage, as is recited in the claims. Bishay et al. specifically teach the electrode pad as configured to be "applied directly to the victim's chest." See column 4, lines 5-6. Applicants submit that the preamble of the instant claims is "necessary to give life, meaning, and vitality" to the claims, and thus "the claim preamble should be construed as if in the balance of the claim." See MPEP § 2111.02. When the claims are read as a whole, taking into consideration the preamble, the claims drawn to implantable lead electrode assemblies are clearly not anticipated by the external electrode pad of Bishay et al..

Regarding claim 60, the Examiner states that if one were to consider the elements 22 and 28 as a "backing layer", then that "backing layer" is attached directly to electrode 24. Bishay et al., however, teach sealing layer 22 and non-conductive layer 28 as separate layers made of different materials and having different properties and functions. The Examiner has not provided any reasoning as to why one would consider the separate layers 22 and 28 as a single layer. Applicants submit that one of skill in the art, upon reading the Bishay et al. reference, would interpret the sealing layer 22 as the "backing layer", and non-conductive layer 28 as a separate

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element contained within the sealing layer. Bishay et al. thus fail to teach each and every element of the claim.

Independent claim 75 recites a backing layer attached to the opposing face of the electrode. Bishay et al. teach an electrode pad in which sealing layers 22, 42, asserted by the Examiner to be the backing layer, are attached to a non-conductive layer 28, 46, not the electrode 24. Bishay et al. thus fail to teach each and every element of claim 75.

Applicants submit that Bishay et al. fail to teach or suggest each and every element of the claims and thus cannot be seen to anticipate the claims. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 62 and 63 are rejected as being unpatentable over Healy in view of Krasnow (US 3,828,766). Claims 69 and 86 are rejected as being unpatentable over Healy. It appears the Examiner intended to reject claims 69, 70, and 86, as it is claim 70 that recites silicone. Claim 65 is rejected as being unpatentable over Bishay et al..

Krasnow is cited for teaching use of polyurethane as a material for a backing layer. Krasnow teaches a disposable adhesive electrode pad for attachment to a patient's skin. Krasnow thus does not provide any motivation or guidance for modifying Healy to achieve an implantable electrode assembly, as is recited in the claims. Krasnow again refers to and includes a gel pad used to provide an interface with the patient's skin. Healy and Bishay et al. both fail to teach each and every element of the independent claims, as discussed above. Thus, the asserted modifications to use silicone as a backing layer do not supply the missing elements.

The Examiner asserts that claim 65 is a product-by-process claim, and thus no criticality has been given to the use of a molding process in the construction of the cover. Applicants submit that Bishay et al. teach sealing layers 22, 42 as preferably coated layers. Bishay et al. teach an electrode assembly for attachment to a patient's skin, thus a flexible coated layer is desirable for the sealing layers 22, 42. Applicants submit that there is no motivation or guidance for one of ordinary skill in the art to modify the device of Bishay et al. to have a molded cover enclosing at least a portion of the bottom of the electrode, as is recited in the claim.

With respect to the Examiner's assertion of a product-by-process claim, Applicants note that claim 1 recites the backing layer disposed over the top of the electrode, and claim 65 calls

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for at least a portion of the cover to be molded and enclosing at least a portion of the bottom of the electrode. Thus the backing layer at least partly holds the electrode in place, as it is on both the top and bottom of the electrode. This structural aspect of the claim must be shown by an element of the cited reference. The Examiner chooses to use either of elements 22 or 42 as the backing layer. One is on one side of the electrode, while the other is on the opposite side. Neither actually covers both the top and the bottom of the electrode. Therefore, at least one element of the claim is not disclosed. If both of elements 22 and 42 are considered together, then it is quite clear that a single molded piece, rather than two separate pieces, provides a distinct structure yielding different results, such that the product-by-process aspect of the Examiner's reasoning would not apply.

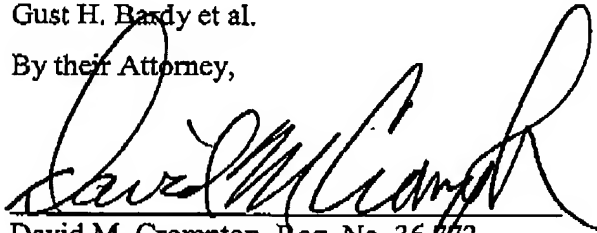
In light of the above remarks, withdrawal of the obviousness rejections, reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

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